CALGB-90203

A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer

ClinicalTrial.gov Identifier: NCT00430183

Study Background

Trial Description

RATIONALE: Drugs used in chemotherapy, such as docetaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Androgens can cause the growth of prostate cancer cells. Antihormone therapy, such as goserelin and leuprolide, may stop the adrenal glands from making androgens. Giving docetaxel and leuprolide or goserelin before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed. It is not yet known whether giving docetaxel and leuprolide or goserelin before surgery is more effective than surgery alone in treating patients with prostate cancer.

PURPOSE: This randomized phase III trial is studying docetaxel and leuprolide or goserelin to see how well they work when given before surgery compared with surgery alone in treating patients with high-risk localized prostate cancer.

Arms:

Arm A: docetaxel + LHRH agonist + surgical intervention: (Experimental): Patients receive six cycles of docetaxel administered every 3 weeks combined with 18-24 weeks of androgen deprivation therapy. During each cycle of chemotherapy, all patients should undergo premedication with dexamethasone 8 mg orally prior to docetaxel. Dexamethasone may also be given intravenously according to institutional guidelines. Patients will also receive androgen deprivation for 18-24 weeks of an LHRH agonist (eg, leuprolide acetate, goserelin acetate). Additional premedication and antiemetics may be given at the physician's discretion and as defined by the protocol. Patients will undergo standard surgical intervention. The surgical procedures will be performed within 60 days of the completion of neoadjuvant therapy. Patients are allowed to receive adjuvant external beam radiation at the discretion of the treating physician and as defined per the protocol. It must be initiated within 6 months of the date of surgery.

Arm B: surgical intervention: (Other): All patients undergo standard surgical intervention. The surgical procedures will be performed within 60 days of randomization. Patients are allowed to receive adjuvant external beam radiation at the discretion of the treating physician and as defined per the protocol. Adjuvant radiation must be initiated within 6 months of the date of surgery.

Objectives:

- Primary:
  - To determine whether treatment with neoadjuvant docetaxel and androgen deprivation therapy prior to radical prostatectomy will increase the rate of 3-year biochemical progression-free survival (bPFS) compared to treatment with immediate radical prostatectomy alone for high-risk prostate cancer patients.
- Secondary:
  - To compare the 5-year bPFS rate, bPFS, disease progression, disease-free survival, and overall survival of patients randomized to the two arms of this trial
  - To determine the safety and tolerability of neoadjuvant docetaxel and androgen deprivation therapy prior to surgery for high-risk patients undergoing radical prostatectomy
  - To compare the impact of neoadjuvant docetaxel and androgen deprivation therapy on time to clinically apparent local disease recurrence and metastatic disease in high-risk patients undergoing radical prostatectomy for clinically localized prostate cancer
  - To compare the impact of neoadjuvant docetaxel and androgen deprivation therapy relative to RP on pathologic tumor stage, frequency of lymph node metastases and positive margin rates for high-risk patients undergoing radical prostatectomy for clinically localized prostate cancer
  - To determine if changes in serum testosterone levels will predict bPFS
  - To determine prospectively whether PSA doubling time (PSADT) is a surrogate endpoint for time to clinical metastases and overall survival.

Patients are followed up to 15 years post-randomization.

Study Milestones:

Primary Completion Date: October 2, 2018

Publication Information:

Analysis Type: Primary

Pubmed ID: 32706639

Citation: J Clin Oncol. 2020 Sep 10;38(26):3042-3050. doi: 10.1200/JCO.20.00315. Epub 2020 Jul 24.

Associated Datasets:

NCT00430183-D1-Dataset.csv (baseline),

NCT00430183-D2-Dataset.csv (toxicity)

Dataset Information:

Dataset Name: NCT00430183-D2-Dataset.csv (toxicity)

Description: Dataset NCT00430183-D2-Dataset.csv (toxicity) is one of 2 datasets associated with PubMed ID 32706639. This dataset contains toxicity information that is presented in the manuscript.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT00430183-D2-Dataset.csv (toxicity) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient identifier	patid		
CTC AE grade	grade	1, 2, 3, 4, 5	
Toxicity	toxicitychar		